

Remarks

This Amendment is in response to the Office action mailed June 7, 2005. Claim 27 is amended, claims 43-55 are canceled, and claims 78-90 added by this Amendment. Claims 27-42 and 78-90 will be pending upon entry of this amendment.

I. Response to Rejection of Claims 27-42

Claim 27 is directed to a chromatography cartridge for use in a chromatography stand. The cartridge has a connector portion adapted for plug in connection with the stand to allow the cartridge to be quickly and easily connected with the stand such that the cartridge is supported in the stand. More specifically claim 27, as amended, specifies a chromatography cartridge for use in a chromatography stand comprising:

a tube for containing chromatography media,

an end cap defining a closed end of the tube, the end cap having an inner face received in the tube and an outer face for connection to said chromatography stand,

the outer face having a connector portion formed therein adapted for plug-in connection with the chromatography stand and shaped to locate the cartridge in a loaded position in the chromatography stand to allow fluid communication with the interior of the tube.

Claim 27, as amended, is unanticipated by and patentable over the references of record, including U.S. Pat. No. 6,171,486 issued to Green et al., because Green et al. does not show or suggest a chromatography cartridge having a connector portion formed in the outer face of an end cap adapted for plug-in connection with a chromatography stand and shaped to locate the cartridge in a loaded position in the stand.

Green et al. disclose a cartridge assembly 22 (Fig. 2) having end caps 40, 42, a cartridge 222 (Figs. 7 and 8) having end caps 240, 242, and a cartridge 422 (Fig. 12) having end caps 440, 442. Cartridge 22 is used with a radial compression module

20 that applies a radial compression force to the cartridge and has a mounting arm 74 extending therefrom for mounting the cartridge to a stand. Each end cap 40, 42 is mounted to the housing 30 of the compression module 20 by a respective band clamp 44, 46 and clamp tightening knobs 48, 50. The exterior axial surface of each end cap 40, 42 which defines the outer axial surface of the cartridge assembly 22 is free from contact with the compression module 20. In the embodiment of Fig. 7, the cartridge 222 may be supported by one or more clamps 220 around the radial exterior surface of the cartridge and connected to a stand 274, or the cartridge may be used with the compression module 20 of Fig. 2. In use with either support structure (e.g., stand 274 or compression module 20), the exterior axial surface of each end cap 240, 242 of cartridge 222 is free from connection to the clamps 220, the stand 274, or the compression module 20. In the embodiment of Fig. 12, the end caps 440, 442 of cartridge 442 are fixed to the cartridge with clamps 444, 446 around the radial surface of the cartridge. The end caps 440, 442 are held in the cartridge 442 by applying an axial load to the clamps 444, 446 that is converted to a radially inward compressive load that deforms portions of the cartridge wall 480 around the end cap to fix the end cap within the cartridge. Figs. 13a thru 16 show various structures for securing the end caps 440, 442 to the cartridge 440 but do not show the assembled cartridge installed in a chromatography stand. For example, stand 552 shown in Fig. 13a is a support structure for holding the cartridge during assembly of the end caps 440, 442 and is not a chromatography stand. In all cases, Green et al. relies on clamping of the radial surface of the cartridge for securement of the cartridge on the chromatography stand or other mounting apparatus.

To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently. Mehl/Biophile Int'l Corp. v. Milgraum, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999). The Office has the initial burden of establishing a *prima facie* case of unpatentability. In re Oetiker, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Applicants note

that the present Office action is devoid of any direct reference to the teachings of Green et al. to support the Examiner's conclusion that that every element of the claim is shown in the cited reference.

Claim 27 recites a chromatography cartridge for use in a chromatography stand having an end cap defining a closed end of a tube having an outer face for connection to said chromatography stand, the outer face having a connector portion formed therein adapted for plug-in connection with the chromatography stand and being shaped to locate the cartridge in a loaded position in the chromatography stand to allow fluid communication with the interior of the tube. It is clear from the teaching of Green et al., that the functional limitation underlined above is not shown or suggested by the teaching of the cited reference. Since the various cartridges of Green et al. are supported by either the compression module 20 or the stand 274 such that the outer faces of the end caps are free from contact with the stand, the outer faces of the end caps are not adapted for plug-in connection with a chromatography stand or shaped to locate the cartridge in a loaded position in the stand. If the Green et al. reference teaches anything about the loaded position of the cartridges disclosed therein, it teaches that the radial surface of the cartridges are supported in a loaded position such that the configuration of the outer face of the end caps of the cartridges is irrelevant to the loading of the cartridge.

The chromatography cartridge of the present invention, having a connector portion that is adapted for plug-in connection with the stand and is shaped to locate the cartridge in the loaded position of the stand, has numerous advantages over the cartridge design in Green et al. that relies on clamping of the radial surface of the cartridge for securement in a stand or other mounting apparatus. The connector portion of the present invention allows the cartridge to be more easily and quickly loaded in a secure position in the chromatography stand. In contrast, the cartridge design of Green et al. requires the placement of the clamp(s) around the external

radial surface of the cartridge and the tightening of the clamp(s) before the cartridge is securely located in the stand or other mounting apparatus. Further, the connector portion of the present invention is universally applicable to cartridges of various diameters so that the various sizes of cartridges each having a connector portion can be securely loaded in the chromatography stand. The cartridges of Green et al. would require a determination of whether the clamp(s) for securement of the cartridge is correctly sized to accommodate the different diameters of the cartridge and replacement of the clamp to accommodate larger (or smaller) diameter cartridges.

Furthermore, the Examiner has failed to set forth a *prima facie* case for obviousness. It is the burden of the Examiner to establish why one having ordinary skill in the art would have been led to the claimed invention by the reasonable teachings or suggestions found in the prior art, or by a reasonable inference to the artisan contained in such teachings or suggestions. In re Sernaker, 217 USPQ 1, 6 (Fed. Cir. 1983). It is well settled, however, that a rejection based on section 103 must rest upon a factual basis rather than conjecture, speculation or assumptions. In re Warner, 154 USPQ 173, 178 (CCPA 1967). It is the burden of the Examiner to establish why one having ordinary skill in the art would have been led to the claimed invention by the express teachings or suggestions found in the prior art, or by implications contained in such teachings or suggestions. Sernaker, 217 USPQ at 6.

In support of the obviousness rejection, the Examiner makes a single statement that "it would have been obvious to optimize the elements of Green (U.S. Patent No. 6,171,486) to enhance separation." Office action, [page 2, 3rd para.]. Applicants submit that the Examiner has neither identified the "elements" of Green et al. nor presented any evidence to establish that such optimization would have been obvious to a person having ordinary skill in the art. In particular, the examiner has failed to show any reasonable expectation, or some predictability, that the end caps of Green et al. have an outer face with a connector portion adapted for plug-in connection

with the chromatography stand and shaped to locate the cartridge in a loaded position in the chromatography stand.

Applicants note that there is no general prohibition regarding the use of functional language in a claim. "A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). There is nothing inherently wrong with defining some part of an invention in functional terms." MPEP §2173.05(g); In re Swinehart, 169 USPQ 226 (CCPA 1971). Moreover, MPEP §2173.05(g) expressly requires functional limitations be considered just like any other limitation in the claim for what they convey to a person of ordinary skill in the art. The M.P.E.P. clearly recognizes the legal basis for functional language set forth in In re Venezia, 89 U.S.P.Q. 149, 150-152 (C.C.P.A. 1976), which sanctioned the use of the claim language "adapted to be positioned," "adapted to be affixed," and "adapted to be fitted." Thus, it is clear that "adapted for" type language should be afforded weight when the language defines structural attributes of the invention.

In the present case (like in In re Venezia), the language of the claim following the phrase "adapted for" does impart a structural limitation to the connector portion. Particularly, the connector portion has to be so structured and dimensioned for plug-in connection with the chromatography stand and to locate the cartridge in a loaded position in the chromatography stand. Green et al. fails to show or suggest such a connector portion. Accordingly, the functional limitation recited in claim 27 must be given consideration in determining the patentability of the claim.

In as much as the Examiner may be relying on inherency for either the section 102 or section 103 rejection, applicants note that in relying upon inherency, the Office must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent feature "necessarily flows from the teachings of the applied prior art." MPEP 2112 citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The fact that a certain result or characteristic

may occur or be present in the prior art is not sufficient for inherency. See MPEP 2112, citing In re Rijckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

Accordingly, applicants submit that the rejections noted in the Office action lack a sufficient basis of fact or reasoning to support the position that Green et al. discloses, explicitly or inherently, a chromatography cartridge for use in a chromatography stand having an end cap defining a closed end of a tube and having an outer face for connection to the chromatography stand, the outer face having a connector portion formed therein adapted for plug-in connection with the chromatography stand and shaped to locate the cartridge in a loaded position in the chromatography stand to allow fluid communication with the interior of the tube.

Claims 28-42 and new claims 78-80 depend directly or indirectly from claim 27 and are submitted as being patentable and nonobvious over Green et al. and the other references of record for substantially the same reasons as claim 27.

Additionally claims 31-36 recite specific dimensions of the connector portion which are not shown or otherwise suggested by the teachings of Green et al. or the other references of record. For this additional reason, claims 31-36 are submitted as patentable over Green et al. and the other references of record.

New claim 78 depends directly from claim 27 and recites that the connector portion extends from the outer face a height that is less than a width of the connector portion. Green et al. and the other references of record fail to show or suggest this feature.

New claim 79 depends from claim 78 and further recites that the connector portion has a flat end surface having a width greater than the height of the connector portion. Green et al. and the other references of record fail to show or suggest this feature.

## II. New Claims 81-90

New claim 81 is submitted as patentable over the prior art of record, including Green et al., in that none of the

references show or suggest a chromatography cartridge in combination with a chromatography stand having the features recited in claim 81, namely:

i) a chromatography stand having a first platen and a second platen each having a recess for locating the cartridge in the stand; and

ii) a chromatography cartridge having a first and second end cap each with a connector portion received in a respective recess for locating the cartridge in a loaded position in the stand wherein the cartridge is supported by an axial force applied by the first and second platens.

It should be noted that the Green et al. reference fails to teach a combination of a chromatography cartridge and a chromatography stand having the features recited in claim 81, including a chromatography cartridge with a first and second end cap each having a connector portion received in a respective recess for locating the cartridge in a loaded position in the stand wherein the cartridge is supported by an axial force applied by the first and second platens. Therefore, claim 81 is submitted as allowable over the prior art.

New claims 82-90 depend directly or indirectly from claim 81 and are patentable over the prior art of record for at least the same reasons as claim 81.

Claim 86 recites that the first and second end cap each further comprise an opening in a respective connector portion for establishing fluid communication with the interior of the tube through a respective one of the first and second platens. Green et al. and the other references of record fail to show or suggest this feature.

III. Conclusion

In view of the foregoing, reconsideration and allowance of claims 27-42 and 78-90 is respectfully requested.

Enclosed is a check and fee transmittal for the one-month extension of time fee. The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment to Deposit Account No. 19-1345 in the name of Senniger Powers.

Respectfully submitted,



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